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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,283	08/11/2000	RICHARD KROCZEK	50125/011001	7620

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EXAMINER

ROARK, JESSICA H

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 11/14/2002

81

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/509,283

Applicant(s)

KROCZEK, RICHARD

Examiner

Jessica H. Roark

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 71-76,78-83,85,86 and 88-148 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 71-75,78-82,85,97,98,100,125-128,133-136 and 141-144 is/are allowed.
- 6) ☒ Claim(s) 76,83,86,88-96,101-124,129-132,137-140 and 145-148 is/are rejected.
- 7) ☒ Claim(s) 99 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 October 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other: _____

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RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 10/17/02 (Paper No. 27), is acknowledged.

Claims 71, 76, 78, 83, 85-86, 88 and 97 have been amended.

Claims 101-148 have been added.

Claims 1-70, 77, 84 and 87 have been cancelled previously.

Claims 71-76, 78-83, 85-86 and 88-148 are pending and are under consideration in the instant application.

2. This Office Action will be in response to applicant's arguments, filed 10/17/02 (Paper No. 27).

The rejections of record can be found in the previous Office Action (Paper No. 26).

It is noted that New Grounds of Rejection are set forth herein.

3. Priority: Acknowledgment is again made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

In addition, Applicant's has provided on 10/17/02 (Paper No. 30) English translations for foreign priority documents DE 197 41 929.1 and DE 198 21 060.4, along with Certificates attesting to the accuracy of these translations.

Since no art rejections are present in the instant case, the Examiner has not determined if either or both of these priority documents fulfill the requirements of 35 U.S.C. 112, first paragraph.

4. Substitute drawings were received on 10/17/02. These drawings have been approved by the Draftsman.

Applicant's amendment, filed 10/17/02, to correct portions of the description of the Drawing in the Specification on pages 9-10 is acknowledged.

However,

on page 9 at line 10, "Fig. 1 shows" should read -- Figs. 1A-B -- ;

on page 9 at line 43 (as amended on 10/17/02), "Figs. 6A-F" should read -- Figs. 6A-6F -- for consistency; and

on page 10 at line 4, "Fig. 14 shows" should read -- Figs. 14A-14B show -- .

Appropriate correction is required.

5. Applicant's provision of the dates for both Tamatani and Tezuka GenSeq Database submissions, W75956 and V53199, is acknowledged. A copy of page 2 of the PTO-1449 filed 8/15/00 (Paper No. 5) showing the dated references is attached.

6. The Krocze Declaration filed on 10/17/02 under 37 CFR 1.132 (Paper No. 28) is acknowledged.

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8. The previous rejection of claims 71-75, 78-83, 85-86, 88-98 under 35 U.S.C. 112, second paragraph, has either been obviated by Applicant's amendment, filed 10/17/02 (claims 78-83, 85-86, 88, 93-96 and 97-98), or is withdrawn (claims 71-75, 78-82, 85 and 89-96 with respect to the recitation of "costimulates" in) in view of Applicant's convincing arguments filed 10/17/02.

9. Applicant's provision in the Response filed 10/17/02 (Paper No. 27, Exhibit D) of a second Statement from Inventor Kroczeck, a person in a position to corroborate the fact that the biological material which is deposited is the biological material specifically identified in the application, has obviated the previous rejection of claims 71-76, 78-83, 85-86, 88-100 under 35 U.S.C. 112, first paragraph, Deposit.

10. Applicant's amendment, filed 10/17/02, has obviated the previous rejection of claims 71-76, 78-83, 85-86 and 88-96 under 35 U.S.C. 112, first paragraph, scope of enablement with respect to a "fragment" of the 8F4 polypeptide or a monoclonal antibody that inhibits a "biological activity" of the 8F4 polypeptide.

New Grounds of Rejection/Objection

Claim Objections

11. Claims 83 and 99 are objected to because of the following informalities:
in claim 83, it appears that "wherein hybridoma produces" should read -- wherein the hybridoma produces -- ;
in claim 99, it appears that the claim should read -- A hybridoma cell line --.
Appropriate correction is required.

Claim Rejections - 35 USC § 112 first paragraph

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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13. Claims 76, 83, 86, 88-96, 101-124, 129-132, 137-140 and 145-148 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The specification as originally filed does not provide support for the invention as now claimed. *This is a New Matter rejection for the following reasons:*

Applicant's amendment asserts that no New Matter has been added and points to the specification at page 16, lines 9-32 for support for the amendment to independent claims 76, 83 and 86 (and dependent claims 88-96, 101-124, 129-132, 137-140 and 145-148).

The disclosure at page 16 lines 9-32 supports the amendment to the claims to recite that proliferation of human T lymphocytes is induced when an antibody to the 8F4 polypeptide and the OKT3 antibody to CD3 are used together. The specification at page 15, lines 14-20, also discloses that in this in vitro assay a goat anti-mouse Ig antibody is coated onto a 96-well plate and the antibody to the 8F4 polypeptide and the OKT3 antibody are loaded onto the 96-well plates (because they are bound by the goat anti-mouse antibody).

While it is acknowledged that coating of the antibodies on a 96-well plate results in antibodies that are "immobilized on a solid surface", the specification does not appear to provide an adequate written description of the limitation "immobilized on a solid surface" because the instant claims now recite limitations which change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the specification or original claims, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112. The specification discloses a particular species of "a solid surface", a 96-well plate. The specification also discloses a single means of immobilizing the antibodies - loading the antibodies onto goat anti-mouse Ig antibodies coated plates.

Disclosure of a single species by itself does not provide adequate written description for a recitation of a genus encompassing the species.

Applicant is required to cancel the New Matter in the response to this Office Action.

It is noted that amending the claims to recite the species disclosed in the specification as filed on page 15 at lines 15-19 would obviate this rejection.

Conclusion

14. Claims 71-75, 78-82, 85, 97-98, 100, 125-128, 133-136 and 141-144 appear to be allowable.

15. Claim 99 is objected to for informalities noted supra, but would appear to contain allowable subject matter.

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16. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica H. Roark, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday, 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
November 7, 2002

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11/14/02